

**NORTH ANDOVER REGULATIONS  
FOR USE OF  
RECOMBINANT DNA MOLECULE TECHNOLOGY**

The Board of Health, Town of North Andover, Massachusetts acting under the authority of Section 31, Chapter II of the General Laws and amendments and additions thereto, and by any other power thereto enabling, has duly made and adopted the following rules and regulations in the interest of and for the preservation of the public health. These regulations have been adopted by unanimous vote of the Board at its regularly scheduled meeting of November 30, 1995, and are effective forthwith upon publication.

1.     **APPLICABILITY**

All activities associated with the construction of recombinant DNA (rDNA) molecules and the use of organisms and viruses containing rDNA molecules within the Town of North Andover shall be performed in strict accordance with these regulations and with the NIH Guidelines as defined in Section 2-C below. The regulations shall govern where they differ from the Guidelines. The regulations do not apply to finished products which contain rDNA molecules and which have been approved by other government regulatory agencies for medical or other purposes.

2.     **DEFINITIONS**

For the purpose of these regulations, the following definitions are adopted:

- a. Large-scale means the use of more than 5000 liters of rDNA culture.
- b. Significant deviation means any deviation that might have an adverse affect on personal or public health.
- c. Guidelines means:
  1. National Institute of Health Guidelines for Research involving Recombinant DNA Molecules published in the Federal Register of May 7, 1986, and any subsequent Federal amendment thereto approved by the Board of Health.
  2. In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect and approved by the Board of Health at the time of such discontinuance shall remain in effect.

3. NORTH ANDOVER BIOSAFETY

- a. The Board of Health Administrator shall serve as the North Andover Biosafety Officer to oversee all use of rDNA in North Andover and to advise the Board of Health.
- b. Specific responsibilities of the NABO shall include:
  1. Establishing policies, procedures and criteria to aid in the implementation of these regulations.
  2. Reviewing all amendments to the Guidelines before submitting recommendations to the North Andover Board of Health for approval.
  3. Reviewing all applications for permits for the use of rDNA in North Andover for compliance with the Guidelines and conformity with such other regulations as the Board of Health may from time to time promulgate.
  4. Reviewing institutions' manuals, worker training programs, health-safety programs and monitoring procedures.
  5. Determining the manner in which institutions and Institutional Biosafety Committees make reports, applications and recommendations to the NABO and the type of information required. Reviewing such reports, applications and recommendations and approving where appropriate. Carrying out site visits to institutional facilities. Approving the community members of the IBC5.
  6. Developing a procedure for members of institutions to report to the NABO violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.

4. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- a. The Institutional Biosafety Committee (IBC), established by the Guidelines, shall have as members, in addition to the corporate representatives, the NABO and the North Andover Board of Health designated representative.
- b. The IBC shall meet on a regular basis, all minutes of the IBC meetings must be forwarded to the NABO or North Andover Board of Health.

- c. The NABO and NABOH designated representatives members of the IBC shall have no financial interest in the institution or any other institution in competition therewith, and such representatives shall be bound to the same provisions and to non-disclosure and non-use of proprietary information and trade secrets as all other members of IBC, except to the extent necessary to alleviate any public health hazard. As used in this regulation, proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.
- d. In accordance with the Guidelines the IBC, acting on behalf of the institution, reviews all rDNA use for compliance with the Guidelines and approves those projects that conform with the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the NABO and the North Andover Board of Health.
- e. All information sent to the North Andover Board of Health and NABO shall have any proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any members of the IBC.

## **5. PERMITS**

- a. All institutions planning to use rDNA must obtain a permit from the Board of Health with the prior approval of the NABO before commencing said technology. All permits are issued for one year and may be revoked for cause.
- b. Institutions seeking such a permit from the Board of Health must first submit the following to the NABO:
  - 1. A plot plan showing the proposed location of the facility and floor plan showing the internal layout of the facility.
  - 2. A list of the major taxonomic groups from which cell lines are obtained or strains are isolated; a pathogen; containment levels, and decontamination procedures to be employed.

3. A certification from the IEC, for any experiment with known human pathogens, that an applicable protocol exists covering resistance to antibiotics, symptoms of infection and emergency incident procedures.
4. A plan for validation of waste systems to assure that surviving rDNA organisms will not be released into the environment.
5. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building.
6. A plan for systematic security of the premises.
7. The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC for all persons engaged in the use of rDNA. Such programs shall include, but shall not necessarily be limited to:
  - a. A pre-employment medical examination for employees.
  - b. Prompt reporting to the IBC of employee illnesses that are potentially related to rDNA use.
  - c. Retention of medical and health records for at least ten years medical or employee health records shall be made available for inspection and may be used for public health studies only with the consent of the employee.
  - d. A training program of safeguards and safety procedures for personnel.
8. The name(s) of the Principal Investigator(s) who shall be responsible for enforcing the policies of the IBC.
9. A plan for orienting representatives of the North Andover Board of Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
10. Written agreement to allow inspection of facilities and pertinent records by the NABO.

- c. The NABO shall review the institution's application for a permit and supporting documents and make a recommendation of the same to the North Andover Board of Health within thirty (30) days of the filing of such application. The North Andover Board of Health shall take final action on the permit application within forty-five (45) days after the application is filed with the NABO. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and the applicant.
- d. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be \$500.00.

## **6. INSPECTION AND REVIEW**

- a. All institutions involved in the use of rDNA shall allow inspection of their facilities, procedures and practices in order to confirm compliance with this regulation.
- b. The North Andover Board of Health shall retain a professionally competent person, agency or institution to perform inspections and reviews. The results shall be reported to the Board of Health, the NABO and the institution involved.
- c. The North Andover Board of Health, its employees, the NABO and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of this ordinance.

## **7. RESTRICTIONS**

- a. rDNA use requiring BL3 containment shall be allowed as provided for in Section 11. rDNA use or experiments requiring BL4 containment shall not be permitted.
- b. The institution shall submit to the NABO documentation of the approved containment level for any experiment for which containment level is not prescribed in the NIH Guidelines prior to the commencement of such experiment.
- c. Large scale rDNA use shall be permitted only with prior review and approval by the NABO.
- d. There shall be no deliberate release into the environment, that is to sewers, drains or the air, of any organisms containing rDNA.

- e. The institution shall report within 24 hours to the NABO, followed by a written report within 5 days to the NABO, any significant deviations from the Guidelines and any significant accidents or illnesses or releases related to the use of rDNA. An additional inspection of facilities and procedures may be deemed necessary by the NABO based upon judgement of the nature and extent of the problem.

## **8. PENALTIES**

- a. Violation of the conditions of this regulation shall subject the violator to a fine of five hundred dollars (\$500.00) per day, and in addition the facility in which the violation occurs may be closed by the Board of Health. Each day of the violation shall constitute a separate and distinct offense.
- b. Once a permit has been issued it may be revoked only after due notice, a hearing, and determination by the Board of Health that the institution involved has materially failed to comply with these regulations, the permit agreements or the guidelines; or if in the opinion of the Board of Health use of rDNA causes a nuisance or adversely affects the public health, safety and welfare in North Andover.

## **9. ASSESSMENTS**

The salaries and expenses paid by the Town for inspections, reviews, staff and consultants for work directly related to carrying out the requirements of these regulations shall be assessed to the institutions holding permits under these regulations. An accounting of these costs will be furnished annually to each institution. Only expenses exceeding the permit fee of \$500.00 shall be assessed.

## **10. SEVERABILITY**

Each part of these regulations is construed as separate, to the end that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

## **11. VARIANCE**

The North Andover Board of Health may vary the application of any provision of these regulations with respect to any particular case when, in its opinion, the enforcements thereof would do manifest injustice; provided, that the decision of the Board of Health is not in conflict with the spirit of

these standards. Any variance granted by the Board of Health must be in writing with a copy available to the public at all reasonable hours in the office of the Town Clerk and in the office of the North Andover Board of Health.

Board of Health

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Gayton Osgood, Chairman

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Francis MacMillan, M.D., Member

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John Rizza, D.M.D., Member